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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,672	06/14/2005	Peter Gerardus Franciscus Cox	I-2002.024 US	4775

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,672	COX ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 04/08/08. Claims 1-8 are currently pending in the application, with claim 8 having being withdrawn. Accordingly, claims 1-7 are being examined on the merits herein.

Applicant's argument with respect to the abstract for containing legal phraseology has been fully considered but is not found persuasive. While the M.P.E.P. clearly states that the abstract should be clear of legal phraseology, it also points out the specific form and legal phraseologies that must be avoided including terms such as "means" and "said". Given that applicant's abstract is devoid of such terms, Examiner has decided to withdraw the objection. Consequently, the objection against the abstract is hereby withdrawn.

Applicant's arguments that Farnsworth does not teach the minimum 20 mg prednisolone unit dose required by applicant's invention has been fully considered but is not found persuasive. The rejections of claims 1-3 and 7 were made over Farnsworth in view of Lohuis under an obviousness rejection. Farnsworth teaches a composition comprising antibacterial agents (i.e. 250 mg of dihydrostreptomycin) and 10 mg of prednisolone diluted in sterile water (i.e. carrier) which led to an increase in leukocyte

count (i.e. no immunosuppression; see pg. 342, left col., paragraph 6; pg. 345, group II, left col. paragraph 2). While Farnsworth did not teach the precise amount of prednisolone, Lohuis et al. teaches the use of 40 mg of prednisolone as an infusion in lactating cows that led to enhanced immune cells level with diminished signs of inflammation (see abstract and fig. 3, for prednisolone i.m.m. 4h after LPS). Moreover, Lohuis et al. demonstrated that administration of 40 mg of prednisolone, 4 h after LPS (i.e. endotoxin) led to an enhanced level of immune cells (i.e. no immunosuppression). Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to use 40 mg of prednisolone along with the antibacterial agent as Lohuis teaches that 40 mg prednisolone led to enhanced immune cell counts. As to applicant's arguments that no apparent expectation existed that greater doses of prednisolone would be advantageous, this statement is not found persuasive as Lohuis clearly demonstrated that usage of greater amount of prednisolone led to enhanced neutrophil and lymphocytes counts. For the foregoing, the rejection of claims 1-3 and 7 are maintained.

Applicant's argument with respect to Farnsworth as not expressly teaching bacterial infection has been fully considered but is not found persuasive. The claims are solely directed to a pharmaceutical composition comprising an antibacterial agent, at least 20 mg prednisolone, and a pharmaceutical carrier. Farnsworth in view of Louis render obvious applicant's invention as they teach a modified composition comprising an antibacterial agent, 40 mg prednisolone and water as the carrier. Moreover,

Examiner further contends that intended use in a product claim is not afforded patentable weight. Moreover, Examiner respectfully points out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963*). Thus, the intended use of ** is not afforded patentable weight. Thus, whether or not Farnsworth in view of Lohuis teaches a study using bacterial infection is irrelevant given that Farnsworth in view of Lohuis clearly render obvious applicant's composition.

Applicant's argument that Farnsworth would have steered a skilled artisan away from using higher concentration has been considered but is not found persuasive. Again, examiner points out that the rejection was made in view of Lohuis who clearly teaches the advantageous use of 40 mg prednisolone in enhancing immune cell counts. Thus, the teachings of Farnsworth in view of Lohuis et al. would have motivated a skilled artisan to vary the concentration and motivated such skilled artisan to try 40 mg of prednisolone in order to see the effects on the immune cells.

Applicant's argument that Lohuis does not study the use of prednisolone to treat an actual bacterial infection has been fully considered but is not found persuasive. Again, examiner points out that the claims are directed to a product which is prima facie over the teachings of Farnsworth in view of Lohuis et al. Moreover, Examiner points out that regardless what Lohuis teaches regarding mastitis, one of ordinary skill in the art would have been motivated to try 40 mg of prednisolone in order to see the effects on the neutrophil and leukocyte counts.

Applicant's argument that Farnsworth in view of Lohuis and further view of Hornish does not provide motivation for developing a composition having at least 20 mg of prednisolone has been fully considered but is not found persuasive. Again, examiner points out that the claims are directed to a product which is prima facie over the teachings of Farnsworth in view of Lohuis et al. Hornish et al. was provided to demonstrate that first generation cephalosporins such as cephapirin or fourth generation cephalosporins such as cefquinome possess greater potency to a broader range of organisms and enhanced transportability. Thus, one of ordinary skill in the art in view of the composition of Farnsworth in view of Lohuis would have been motivated to utilize cephapirin or cefquinome as the antibacterial agents as Hornish teaches that the aforementioned agents are more potent to a variety of organisms. For the foregoing reasons, Examiner maintains that Farnsworth in view of Lohuis and in further view of Hornish are prima facie obvious over claims 4-6.

For the foregoing reasons, the rejections of claims 1-3 and 7 and claims 4-6 under 35 U.S.C, § 103 (a) remain proper and are maintained. For applicant's convenience, the following 103 (a) Final rejections are restated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, and 7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Farnsworth et al. (Canadian J. of Comp. Med. July 1975, Vol. 39, Iss. 3, pp. 340-348, previously cited) in view of Lohuis et al. (J. Dairy Sci., 1989, Vol. 72, pp. 75-98, previously cited).

Farnsworth et al. teaches a composition comprising an antibiotic (i.e. antibacterial agent) and steroid treatment in cows (see abstract and Materials and Methods section, pp. 341, paragraph 1, line 1). In particular, Farnsworth discusses the use of sterile water (i.e. carrier) as the diluent for 250 mg dihydrostreptomycin (i.e. antibacterial agent vs. instant claim 7) and 10 mg of prednisolone (see Materials and Methods section, pp. 342, paragraph 6, lines 1-8) injected into the teat cistern (i.e.

mammary glands) of cows (Materials and Methods section, pp. 342, paragraph 6, lines 14-15).

Farnsworth et al. does not specifically teach a composition comprising at least 20 mg of prednisolone per unit dose.

However, Lohuis et al. teaches the use of 40 mg of prednisolone as an intramammary infusion in lactating cows (see abstract and animal section of Materials and Methods, pp. 241).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to discover the optimum or workable ranges of prednisolone through routine experimentation as evidenced by Lohuis to arrive at a therapeutically effective composition since Farnsworth et al. teaches a composition of prednisolone and antibiotics in an aqueous solution. Given that Farnsworth teaches a prednisolone and antibiotics composition, one of ordinary skill would have been motivated to modify the composition of Farnsworth et al. with the expectation of providing a composition that is therapeutically effective comparable to applicant's invention.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farnsworth et al. (Canadian J. of Comp. Med. July 1975, Vol. 39, Iss. 3, pp. 340-348, previously cited) in view of Lohuis et al. (J. Dairy Sci., 1989, Vol. 72, pp. 75-98, previously cited) as applicable to claims 1-3, and 7 above and in further view

of Hornish et al. (Current Topics in Med. Chem. July, 2002, Vol. 2, Iss. 7, pp. 717-731, previously cited).

The Farnsworth and Lohuis references are as discussed above and incorporated by reference herein. However, Farnsworth and Lohuis do not address the use of specific cephalosporins as the antibacterial agents in the aforementioned composition.

Hornish et al. teaches the use of cephalosporins for treatment of mastitis infections and/or respiratory disease in cattle (see abstract). Hornish further teaches the use of first generation cephalosporins such as cephapirin against gram positive pathogenic cocci (see table 2 and pp. 719, paragraph 1) or the use of fourth generation cephalosporins such as cefquinome with greater potency to a broader range of organisms and enhanced transportability across the blood-membrane barrier (see table 2 and pp. 719, paragraph 4).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to combine the composition of Farnsworth and Lohuis in view of the knowledge of cephalosporins as potent antibacterial agents provided by Hornish. Given that Farnsworth teaches a composition of prednisolone and antibacterial agent and Lohuis discloses an effective dosage of prednisolone, and Hornish discloses the use of cephalosporins as potent antibacterial agents, one of ordinary skill would have been motivated to combine the composition of Farnsworth et al. and Lohuis et al. with the

disclosure of Hornish et al. with the expectation of providing a potent composition that is therapeutically effective.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

06/30/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617